

REMARKS

A. Status of the claims

Claims 3, 7 and 11-20 were previously canceled; therefore, claims 1-2, 4-6 and 8-10 are currently pending and under examination.

B. Rejections under 35 U.S.C. §112, first paragraph (enablement), are moot

Claims 1, 2, 4-6 and 8-10 remain rejected under 35 U.S.C. §112, first paragraph, as assertedly lacking enablement commensurate with the scope of the claims. Applicants respectfully traverse the rejection and request reconsideration of the claims in view of the following arguments.

In the rejection the Examiner states that the specification as filed does not reasonably provide enablement for “1) a method of determining differentiation status; and 2) a method of detecting, isolating or sorting mammalian embryonic stem cells for stem cells undergoing differentiation wherein the absence of 5T4 expression indicates undifferentiated stem cells,” (page 3 of the instant rejection). The Examiner argues that “detecting the differentiation status” encompasses a method that is capable of discerning undifferentiated embryonic stem cells, stem cells that have just entered process of differentiation, intermediate precursor cells, last stage differentiating cells, and differentiated cells.

It appears that the Examiner believes that 5T4 would not be expressed on fully differentiated cells. The only evidence cited by the Examiner in support of the rejection is Boyle et al. (Human Gen. (1990) 84:455) which indicates, at column 1, paragraph 1 that “[i]n **adult tissues**, 5T4 expression is limited to a few epithelial cell types,” (emphasis added). The Examiner states that Boyle et al. teaches 5T4 antigen expression is present only in trophoblast cells and in a variety of carcinoma cells.

The Boyle publication provides no insight into the workings of the present invention because, Boyle does not provide any disclosure concerning the 5T4 expression status of mammalian embryonic stem cells that are differentiating. All claimed methods concern cell detection (or cell separating) methods with a defined population of embryonic

stem cells. For example, in claims 1 and 8 the subject cell population is defined as “mammalian embryonic stem cells.” Claim 9 concerns cell separation methods with “a mixture of undifferentiated mammalian embryonic stem cells and mammalian embryonic stem cells *undergoing differentiation*. Therefore, detecting differentiation status in such a cell population would *not* encompass detecting (or not detecting) 5T4 antigen on differentiated, adult cells because such cells would not be comprised in the cell population subjected methods as claimed. Hence, because all claimed methods concern a population of cells comprising either embryonic stem cells or a mixture of undifferentiated mammalian embryonic stem cells and mammalian embryonic stem cells *undergoing differentiation*, Boyle’s teaching and the Examiners concerns regarding the lack of 5T4 expression on fully differentiated cells are not germane to the question of enablement of the methods *as claimed*. In view of the foregoing, Applicants assert that the claims as presented are fully enabled by the specification and the rejection under 35 U.S.C. §112, first paragraph, is believed to be moot.

C. Conclusion

In view of the above arguments, Applicants believe the pending application is in condition for allowance. The Examiner is invited to contact the undersigned with any questions or concerns.

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Respectfully submitted,

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